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EXAMINER ARCHIE, NINA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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SFOJSHPAIR@dw.com
sf-patents@dw.com

Office Action Summary**Application No.**

10/595,909

Applicant(s)

SCHROTZ-KING ET AL.

Examiner

NINA ARCHIE

Art Unit

1645

Period for Reply -- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) ____ is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/87)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed on 12-5-2011. Claims 1-2 and 7 are amended. Claims 9-11, 15-22, 28-35, and 40-55 are withdrawn from consideration. Claims 36-39 are cancelled. Claims 1-35 and 40-55 are pending. Claims 1-8, 12-14, and 23-27 are under examination.

Election/Restrictions

2. Applicant's election without traverse of claims 1-8, 12-14, and 23-27 are acknowledged in the reply filed on December 5, 2011 is acknowledged. Claims 9-11, 15-22, 28-35, and 40-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected (claims 28-31), (claims 9-11, 32, and 34-35), (claims 40 and 42), (claims 41 and 42), (claims 43-44 and 46-47), (claim 45), (claim 48), (claim 49), (claim 50), (claims 51-52), (claim 53), and (claims 54-55) there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 5, 2011. Claims 1-35 and 40-55 are pending. Claims 1-8, 12-14, and 23-27 are under examination.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

4. The drawings filed on date on 5/18/2006 in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

5. The information disclosure statements filed on 6/18/2010, 9/18/2006, and 9/15/2006 have been considered. Initialed copies are enclosed.

Claim Objections

6. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

7. Claims 1 and 2 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 8-9 and 11-12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are directed to a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

To adequately describe the genus of vaccine composition comprising an comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, applicant must adequately describe the antigenic determinants (immunoepitopes) in said vaccine compositions that convey the ability to be protective. The issue here is that the skilled artisan cannot reasonably and readily envision that Applicant is in possession of a vaccine composition for any disorder. In the absence of a vaccine composition, Applicant would not also be in possession of said vaccine composition comprising the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence.

The specification discloses working examples with different combinations of antigens and controls including SEQ ID NO: 43 (i.e. CJ0420) (see Figure 3 pg. 9 and pgs. 62-64). However, the data does not support that the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence alone will even work at all in a vaccine. In the instant case, nothing exists in the specification to demonstrate that Applicant is in possession of a vaccine composition comprising sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence. In the absence of any evidence demonstrating that Applicant is in possession of the primary active ingredient for the claimed invention, a vaccine composition comprising sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, the skilled artisan cannot reasonably conclude or recognize that Applicant is in possession of the claimed invention at the time the invention was filed.

Moreover a vaccine is defined as "a prophylactic or therapeutic material containing antigens derived from one or more pathogenic organisms which, on administration to man or animal, will stimulate active immunity and protect against infection with these or related organism (i.e. produce protective immunity)." (The Dictionary of Immunology, Herbert et al eds, Academic Press, 1995).

Moreover the specification fails to disclose the protective immunopeptide(s) in a vaccine composition comprising an antigen with an immunostimulatory oligonucleotide. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of the vaccine composition comprising sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence aforementioned above to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of a vaccine composition sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence possessing the recited functions (prevention). Therefore, the specification does not set forth a disclosure of any relevant identifying characteristics, such as the disclosure of complete or partial structure of a vaccine composition. In the instant case, the specification has not set forth the physical and/or chemical properties, and function characteristics that the composition must have to retain such therapeutic activities.

The specification further does not disclose distinguishing and identifying features of a representative number of members of the genus to which the claims are drawn, such as a correlation between the structure and its recited function (i.e. prophylactic or therapeutic material), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine.

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and

determined that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). See also *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) ("[T]here cannot be a reduction to practice of the invention without a physical embodiment which includes all limitations of the claim."); *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588,593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose."); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996) (determining that the invention will work for its intended purpose may require testing depending on the character of the invention and the problem it solves).

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104).

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (*Id.* at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus.

Although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrashekar et al., US Patent 6,248,329, col. 1, lines 35-

41). It is well recognized in the vaccine art, that it is unclear whether an antigen derived from a pathogen will elicit protective immunity. Ellis (Chapter 29 of Vaccines, Plotkin, et al. (eds) WB Saunders, Philadelphia, 1998, especially p. 571, paragraph 2) exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies..., and thus protect the host against attack by the pathogen." Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of vaccine compositions comprising an antigen with an immunostimulatory oligonucleotide with the claimed characteristics, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of A composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X₁ is V or A, and X₂ is A or T, and X₃ is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X₁ is V or A, and X₂ is A or T, and X₃ is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine is not deemed representative of the genus of vaccine composition capable of protection aforementioned above, to which the claims refer and therefore the claimed invention is not properly disclosed.

Claim Rejections - 35 USC § 112

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabled for a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention: The instant claims are drawn to a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine (claim 12), wherein the composition comprises an immunogenic carrier (claim 13), wherein the composition comprises an adjuvant (claim 14).

Breadth of the claims: The breadth of the claims is very broad and the quantity of experimentation required is undue. The claimed invention is drawn to vaccine and as result

vaccine is correlated to prevention. A vaccine by definition must provide protection against an infection demonstrable by challenge experiments. The claims encompass all vaccine compositions comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine. The claimed invention is directed to a composition with the intended use of the composition as a vaccine composition, wherein the claims does not limit the composition to a vaccine composition for any particular disease or disorder. In view of the types of diseases or disorders such as cancer, HIV, and bacterial etc, encompassed by the claims.

Guidance of the specification/The existence of working examples:

The specification discloses working examples with different combinations of antigens and controls including SEQ ID NO: 43 (i.e. CJ0420) (see Figure 3 pg. 9 and pgs. 62-64). However, the data does not support that the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence alone will even work at all in a vaccine. The claimed invention is drawn to vaccine and as result vaccine is correlated to prevention. A vaccine by definition must provide protection against an infection demonstrable by challenge experiments. The specification does contain working examples, however, none are directed at evidencing or indicating that a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A can be used as a vaccine for any disease or disorder alone nor an antigenic fragment or variant thereof the composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A. Because the data as set forth supra does not demonstrate that the composition confers "protection". Therefore the data fails to show vaccine protection. Therefore, one skilled in the art would not accept on its face the examples given in the specification as being correlative or representative of a successful model. The working examples do not disclose any empirical data or results indicative of a vaccine and the specification is devoid of any teaching of a vaccine composition.

State of the art:

Although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrashekar et al., US Patent 6,248,329, col. 1, lines 35-41). It is well recognized in the vaccine art, that it is unclear whether an antigen derived from a pathogen will elicit protective immunity. Ellis (Chapter 29 of Vaccines, Plotkin, et al. (eds) WB Saunders, Philadelphia, 1998, especially p. 571, paragraph 2) exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies..., and thus protect the host against attack by the pathogen. For the reasons set forth supra, the state of the art has limitations to a vaccine composition aforementioned above and the state of the art is unpredictable with regard to any vaccine composition as set forth supra.

In conclusion, the claimed invention is not enabled for any composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament, wherein the claim also contain language that directs the use of the composition as a vaccine. As noted above, the claimed invention is directed to a composition with the intended use of the composition as a vaccine composition, wherein the claims do not limit the composition to a vaccine composition for any particular disease or disorder.). The claimed invention is drawn to vaccine and as result vaccine is correlated to prevention. A vaccine by definition must provide protection against an infection demonstrable by challenge experiments. The specification does contain working examples, however, none are directed at evidencing or indicating that a composition comprising an antigen and said oligonucleotide can be used as a vaccine for any disease or disorder because the data as set forth supra does not demonstrate that the composition confers "protection". The state of the art teaches that there are limitations to a vaccine composition and the state of the art is unpredictable. In view of the lack of support in the art and specification for an effective vaccine, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the claims are not enabled. As a

result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed vaccine composition.

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-8, 12-14, and 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to independent claim 1, the claim recite the phrase “wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A” in the composition as claimed. However, the sequence listing give specific positions of the variable X that is not indicated in claims. However, neither the claim nor the specification clearly defines nor sets forth the meaning or means to assess “wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A”. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of “wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A” nor how to assess such. It is unclear how to interpret what is considered “wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A” in relation to the sequence listing in the specification with regard to SEQ ID NO: 43 and inasmuch as it is not a recognized term and not defined in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 6-7, 12, and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (WO2002/077183A2 Date October 3, 2002).

The claims are drawn to a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is V or A, and X_2 is A or T, and X_3 is T or A, or comprises an antigenic fragment or variant of said sequence, for use as a medicament (claims 1 and 2), wherein the variant has at least 95% sequence identity to said sequence (claim 3), wherein the antigenic fragment comprises less than 99% sequence identity to said sequence (claim 4), wherein the antigenic fragment comprises 6 or more consecutive amino acids of said sequence (claim 6), wherein the antigenic fragment comprises one or more residues of a fragment selected from the group consisting of SEQ ID NOs:74-81 (claim 7), wherein the medicament is a vaccine (claim 12), wherein the composition comprises a pharmaceutically-acceptable carrier (claim 23), wherein the composition is suitable for systemic administration (claim 24), wherein the composition is suitable for intravenous, intramuscular, or subcutaneous administration (claim 25), wherein the composition is suitable for oral administration (claim 26), wherein the composition is suitable for intranasal administration (claim 27).

Wang et al teach to a composition comprising a polypeptide which comprises the sequence of SEQ ID NO: 43, wherein X_1 is A, and X_2 is A, and X_3 is T, or comprises an antigenic fragment or variant of said sequence, wherein the variant has at least 95% sequence identity to said sequence, wherein the antigenic fragment comprises less than 99% sequence identity to said sequence, wherein the antigenic fragment comprises 6 or more consecutive amino acids of said sequence, wherein the antigenic fragment comprises one or more residues of a fragment selected from the group consisting of SEQ ID NOs:74-81, (see STIC attachment and claim 25).

As to dependent claims 24-27 reciting limitations, a composition, wherein the composition is suitable for systemic administration (claim 24), wherein the composition is suitable for intravenous, intramuscular, or subcutaneous administration (claim 25), wherein the composition is suitable for oral administration (claim 26), wherein the composition is suitable for intranasal administration (claim 27). Said recitations are considered an intended use and thus is given no patentable weight on the composition. Therefore the claims are drawn to a composition.

Conclusion

11. Claims 5, 8, and 13-14 are objected to as being dependent on a rejected base claim. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie
Examiner
Art Unit 1645

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1645